

021450-Original-Approval-Pkg

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

**APPLICATION NUMBER:
21-450**

Trade Name: Zomig Nasal Spray

Generic Name: zolmitriptan

Sponsor: AstraZeneca Pharmaceuticals LP

Approval Date: September 30, 2003

Indications: For the acute treatment of migraine.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-450

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	X
Final Printed Labeling	X
Medical Review(s)	X
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	X
Statistical Review(s)	X
Microbiology Review(s)	X
Clinical Pharmacology and Biopharmaceutics Review(s)	X
Administrative Document(s)	X
Correspondence	X

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-450

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-450

Judy W. Firor
US Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
PO Box 8355
Wilmington, DE 19850-8355

Dear Ms. Firor:

Please refer to your new drug application (NDA) dated March 27, 2003, received March 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zomig (zolmitriptan) Nasal Spray.

We acknowledge receipt of your submissions dated April 17, April 25, August 29, and September 30, 2003 .

The March 27, 2003 submission constituted a complete response to our December 19, 2002 action letter.

This new drug application provides for the use of Zomig (zolmitriptan) Nasal Spray for the acute treatment of migraine.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved NDA 21-450." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your phase 4 commitment, as discussed in a teleconference held on August 28, 2003 and in your letter dated August 29, 2003, to provide the following information to support approval of (b)(4)----- spray devices.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.